IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

NORTHERN DIVISION

BRAD RASMUSSEN and JULIE RASMUSSEN, Plaintiffs, v. **ALTIUS HEALTH PLANS, INC.,** Defendant.	**MEMORANDUM DECISION AND ORDER** Case No. 1:10CV95DAK

This matter is before the court on cross motions for summary judgment and cross motions to strike filed by Plaintiffs Brand and Julie Rasmussen and Defendant Altius Health Plans, Inc. After the motions were fully briefed, the court held a hearing on the motions on August 3, 2011. At the hearing, Plaintiffs were represented by Brian S King, and Defendant was represented by Daniel Steele. The court took the motions under advisement. Having fully considered the motions, memoranda, affidavits, and exhibits submitted by the parties as well as the facts and law relevant to this motion, the court enters the following Memorandum Decision and Order.

BACKGROUND

In this case, Plaintiffs Brad and Julie Rasumssen appeal Defendants' denial of health insurance benefits for Julie's Ketamine Infusion Therapy. Altius is the insurer and plan administrator for Brad Rasmussen's employer, Aqua Engineering. Brad's daughter, Julie, a beneficiary of the plan has Complex Regional Pain Syndrome ("CRPS") also known as Reflex

Sympathetic Dystrophy ("RSD').

In November 2007, the Rasmussens traveled to Hot Springs, Arkansas, to meet with Dr. Ronald Harbut at St. Joseph's Mercy Health Center about using Ketamine Infusion Therapy to treat Julie's CRPS. Ketamine is an FDA-approved drug but Dr. Harbut noted that using Ketamine Infusion Therapy to treat CRPS is "a non-conventional treatment option using a prolonged low-dose infusion of intravenous ketamine." Harbut provided Julie with a treatment plan and recommendations. Plaintiffs did not notify Altius of this doctor visit and did not submit a claim to Altius for the visit.

On March 25, 2008, Julie was admitted to St. Joseph's for a five-day Ketamine Infusion Therapy. Neither the hospital nor the Rasmussens notified Altius of this treatment before or during the treatment. On March 30, 2008, shortly after Julie had been discharged from the hospital, she was re-admitted on an emergency basis for complications related to the Ketamine Infusion Therapy. On March 31, 2008, Altius was notified for the first time regarding Julie's admittance for complications related to the Ketamine Infusion Therapy. After reviewing Julie's records from St. Joseph's, Altius' Medical Director, Dr. Dot J. Verbugge, denied coverage for Julie's Ketamine Infusion Therapy and the readmission on the grounds that it was a complication of a non-covered benefit.

The Altius Plans Inc. Group Service Agreement for Aqua Engineering ("GSA") excludes coverage for "experimental" or "investigational" drugs and services: ""drugs, treatments, procedures, or devices that are Experimental, Investigational, unproven, not generally accepted, or part of research study, as more fully described in Section V of this Agreement." Section V of the GSA states, in pertinent part:

A health product or service is deemed Experimental or Investigational if one or more of the following conditions are met:

1. Any drug not approved for use by the Food and Drug Administration (FDA); any drug that is classified as IND (investigational new drug) by the FDA; any drug requiring Prior Authorization that is proposed for off-label prescribing;

. . . .

4. Any health product or service that is considered not to have demonstrated value based on clinical evidence reported by Peer-Review Medical Literature and by generally recognized academic experts.

The GSA contains an integration clause stating that "[t]his Agreement embodies the entire Agreement of the parties. There are no promises, terms, conditions, or obligations other than those contained herein. This Agreement (including the application, enrollment forms, medical benefits brochure, and all other endorsements, exhibits, addenda, or amendments, if any) supercedes all prior communications, representations, or agreements between parties, either written or verbal."

Appendix A of the GSA is entitled "Benefits, Copayments, Limitations, and Exclusions." The Limitations and Exclusions section of Appendix A states that the following are excluded from coverage under the benefit plan: "[e]xperimental or investigational treatment, procedures, tests, equipment, or facilities, or any health care service which is still undergoing evaluation and review and is not accepted as standard treatment in the medical community."

On April 4, 2008, Altius sent Julie a letter denying benefits for Julie's Ketamine Infusion Therapy and her emergency readmission. The letter noted that St. Joseph's had requested

authorization for inpatient hospitalization for admission dated March 25, 2008. The reason given for the denial was "the treatment recommended is considered investigational/experimental (see investigational/experimental definition in your member handbook) and an exclusion under your benefit plan." The letter also stated that her readmission was denied because it was the result of complications of a non-covered service.

Brad Rasmussen sent Altius a letter, dated May 25, 2008, requesting an appeal of the denial of coverage. Brad argued that the treatment did not fall within the investigational/experimental provisions of the contract and he sent a list of various articles regarding the treatment. On June 30, 2008, Altius reviewed the Ketamine Infusion Therapy and emergency readmission as separate appeals. Altius clinically reviewed the Ketamine Infusion Therapy and had the Administrative Appeals Committee review the emergency readmission.

On July 3, 2008, Jeff E. Oken, a Medical Consultant, who is board certified in physical medicine and pain management, reviewed the appeal and recommended upholding the denial of coverage for Ketamine Infusion Therapy. Dr. Oken concluded that "Ketamine inpatient infusion therapy is not at this point in time accepted as standard treatment in the medical community." On July 3, 2008, the Administrative Appeals Committee upheld the denial of the emergency readmission because the services were related to non-covered services.

On July 15, 2008, Altius sent Brad a letter informing him that the Committee had upheld the original denial of coverage based on the facts of the case and the clinical review criteria. Altius relied on the language in Appendix A to the GSA. Brad was also informed that the emergency readmission denial was being upheld because it related to a non-covered service.

On July 17, 2008, Brad telephoned Altius and requested information used to make the

determination to deny his appeal. On August 5, 2008, Altius sent Brad a letter outlining information used in denying the claim and first level appeal. In a letter, dated September 7, 2008, Brad requested a second level appeal of the denial of benefits. In that letter, Brad acknowledged receiving information from Altius. Brad argued that information he received contained a "Policy for Experimental" that he believed differed from the GSA definition of investigational/experimental. Brad then quoted from the GSA definition, including only the first sentence regarding drugs. Brad asked Altius to re-evaluate the appeal based on the correct definition.

On September 26, 2008, Altius provided materials to MCMC, LLC for an independent medical review of the coverage denials. The referral form requested that the reviewing physician answer two questions: "(1) was initial admit for Ketamine treatment considered I/E for this service? And (2) Was second admit 3/30/08 d/t [due to] complications of Ketamine treatment?" On September 29, 2008, Lisa Nocera, M.D., who is board certified in Anesthesiology and Pain Medicine, reviewed the appeal. She upheld the denial for the Ketamine therapy because it is investigational/experimental and she upheld the denial of coverage for the readmission because it was related to the therapy.

On October 17, 2008, Altius sent Brad a letter upholding the denial of benefits. On January 4, 2009, Brad sent Altius a letter regarding the rejection of the second appeal and requesting Altius to send the appeal to an independent reviewer. On January 13, 2009, Altius again requested MCMC to provide another independent reviewer. The documents submitted were reviewed by Paul Lafavore, M.D., who is board certified in Anesthesiology and Pain Medicine. Dr. Lafavore upheld the denial of coverage. Dr. Lafavore noted the many side effects

associated with the therapy and stated that Ketamine is not recommended for diagnostic or therapeutic use until additional studies demonstrating its clinical efficacy have been reported. He concluded that the use of the therapy in this case was investigational.

On January 22, 2009, Altius sent Brad a letter informing him of the results of Dr. Lafavore's review. On March 30, 2009, in response to a complaint Brad lodged with the Utah Department of Insurance ("DOI") and at the DOI's request, Altius requested further independent medical review. Altius again sent materials to MCMC for another independent review. In addition to the documents sent to the previous reviewers, Altius sent portions of the GSA relevant to investigational/experimental procedures.

Thomas W. Sinson, III, M.D., Ph.D., who is board certified in Anesthesiology and Pain Medicine, reviewed the documents and concluded that the "use of intravenous Ketamine is not generally considered to have demonstrated value based on clinical evidence." He opined that there were no well-conducted randomized controlled studies, there appears to be only a brief response to the treatment, and published reviews have generally opined that it is a promising but unproven treatment. He agreed that coverage should be denied.

Altius sent Brad a letter, dated April 30, 2009, notifying him of the Independent Review Determination. In a letter, dated May 21, 2009, Altius summarized for Brad the course and results of the various appeals and asked him to contact Altius' Appeals and Grievances Department if he had any additional questions. On June 15, 2010, Brad filed the present action in this court.

DISCUSSION

Cross Motions for Summary Judgment

Plaintiffs argue that Altius wrongfully denied their claim for health benefits, whereas Altius argues that its decision denying benefits should be upheld. Before reaching the merits, the parties dispute what standard of review this court should apply in its review of Altius' decision.

I. Standard of Review/Conflict of Interest

The parties dispute whether the case should be reviewed under a de novo standard or the arbitrary and capricious standard. ERISA itself does not specify the standard of review that should be used. However, the United States Supreme Court has held that a denial of benefits challenged under ERISA, "is to be reviewed under a de novo standard unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989). When the plan grants discretionary authority to the administrator, the denial of benefits is reviewed under the "arbitrary and capricious" standard. *Chambers v. Family Health Corp.*, 100 F.3d 818, 825 (10th Cir. 1996).

The parties do not dispute the level of deference given to Altius in the plan documents. Rather, Plaintiffs focus on the conflict of interest and procedural irregularities. Plaintiffs contends that Altius' conflict of interest together with significant procedural irregularities call for a significantly reduced degree of deference in this court's review.

The Tenth Circuit has said that although the arbitrary and capricious standard requires the court only to ask whether the interpretation of the plan was reasonable and made in good faith, courts dial back deference "if 'a benefit plan gives discretion to an administrator or fiduciary who

is operating under a conflict of interest." In such a situation, that 'conflict should be weighed as a factor in determining whether there is an abuse of discretion.'" *Weber v. G.E. Life Assur. Co.*, 541 F.3d 1002 (10th Cir. 2008). The Tenth Circuit still applies its sliding scale approach where "the reviewing court will always apply an arbitrary and capricious standard, [but] will decrease the level of deference given . . . in proportion to the seriousness of the conflict." *Id.*

Insurers of ERISA plans may have the deference normally accorded them under an abuse of discretion standard of review decreased in light of their inherent, structural conflict of interest. *Metropolitan Life Ins. Co. v. Glenn*, 128 S. Ct. 2343 (2008). The Supreme Court has directed that this conflict should be considered as one of many factors by courts in determining whether an abuse of discretion occurred, but has also made clear that the actual abuse of discretion standard remains unchanged. *Glenn*, 554 U.S. 105 (2008). Whether the conflict plays a major or minor role in the review depends on the circumstances of the case.

Plaintiffs argue that in this case the same inherent structural conflict of interest is present as existed in *Glenn*. Altius is an insurer competing with other insurers in an open market place and it would not exist if it consistently paid out more in claims than it collected in premiums. Plaintiffs contend that the pressure on Altius to keep payment of claims as low as possible, so as to compete successfully with its insurance peers, is significant. Altius acknowledges that it is both the maker of claims decisions and the claims payor. Although Altius admits that the conflict exists, it contends that there should be no significant decrease in the level of deference under the facts of this case.

The parties dispute whether Altius tried to mitigate the effect of its structural conflict. Altius points to the number of independent reviews it had conducted in relation to Plaintiffs'

claim. Plaintiffs, however, take issue with Altius' use of MCMC as independent reviewers because the claim that MCMC essentially becomes employed by Altius to do the review. Plaintiffs contend that the conflict extends to MCMC because its stated purpose is to serve its clients, the insurers. However, MCMC essentially provides the insurance companies with a clearing house of doctors who can conduct independent reviews. MCMC provides insurance companies with a means of finding doctors with various specialties. There is no evidence to suggest, however, that MCMC influences its independent reviewers. MCMC merely puts the insurance company in contact with doctors who can perform the review. Unless there is clear evidence that MCMC attempts to influence the independent reviews conducted by the doctors it refers to insurance companies, the court will not assume that the conflict extends to MCMC or that the doctors referred by MCMC are not , in fact, independent.

Plaintiffs further argue that there were procedural irregularities--such as Altius providing the reviewers with past reviews and providing them with its own definition and not the plan's definition of investigational/experimental–that resulted in decisions favorable to Altius and should be considered in determining the level of deference to give to Altius' benefits decision. Altius argues that the alleged procedural irregularities are not irregularities and are not significant.

Plaintiffs argue that the adverse decisions themselves are not only wrongly decided but should also be considered for purposes of determining the standard of review. But an adverse decision is not a procedural irregularity merely because Plaintiffs think it is wrongly decided. Altius gave full explanations for each of its decisions. If there was no explanation or analysis provided for the decision, an adverse decision may qualify as demonstrating a procedural

irregularity. But, in the case of a fully reasoned explanation, there is no basis for concluding that the adverse decision is a procedural irregularity.

In addition, Altius provided the independent reviewers with the findings of past reviewers and the letters from Brad Rasmussen taking issue with those decisions. The materials provided to the reviewers appear to have been even-handed and informative as to the points of disputes between the parties. There is nothing inherently wrong with giving an new reviewer the findings of a past reviewer when it is included with information from both sides.

Finally, Altius appears to have provided reviewers with its own description of investigational/experimental based on the plans provisions regarding those terms. The use of a separate source of information does not, in itself, appear to be such a procedural irregularity as to be a basis for questioning the process being afforded. The information is consistent with the plan's provisions. In addition, Altius is the ultimate reviewer of the claim. The medical reviewers do not make the decision under the terms of the plan. The medical reviewers merely make their medical assessment and Altius applies that assessment to the terms of the plan. There is no need for the medical reviewers to have the exact language of the plan in front of them. In fact, if an insurer provided the exact language, a plaintiff could just as easily argue that the insurer was attempting to tell the medical reviewer exactly what to find. The argument can be made both ways. The court, therefore, does not believe that a separate definition of investigational/experimental demonstrates a procedural irregularity that would require a decrease in the level of deference afforded to Altius.

After considering each of Plaintiffs' claims regarding Altius' conflict of interest, the court concludes that there should be a slight decrease in the deference afforded based on the fact that

Altius decides the claims and is the claims payor. However, Plaintiffs have not demonstrated the need for a significant decrease in the level of deference.

II. Merits

The parties dispute whether Altius's decision to deny benefits for the Ketamine Infusion Therapy on the grounds that it is investigational and/or experimental is supported by the GSA. The parties' disagree on the relevant provisions in the GSA and the application of those provisions.

As set forth above, the GSA's definition of investigational and experimental includes four general categories. Plaintiffs initially focused mainly on the first category. But both parties now agree that the main focus for their dispute is in connection with the fourth category. The fourth category excludes any service that is "considered not to have demonstrated value based on clinical evidence reported by peer-reviewed medical literature and by generally recognized academic experts."

Plaintiffs argue that Brad provided Altius with a list of twenty academic papers and studies stating that Ketamine Infusion Therapy is accepted within the medical community and has a demonstrated value to individuals with RSD. However, Dr. Nocera concluded that there was "an insufficient number of controlled studies showing efficacy and insufficient scientific evidence to support that Ketamine treatment is safe." Dr. Lafavore concluded that "more formal studies are needed to address the efficacy and safety of ketamine for neuropathic pain." Dr. Stinson, the final independent reviewer, specifically stated that in his medical opinion there was no demonstrated value for the therapy. Moreover, Plaintiffs' treating physician, Dr. Harbut, referred to the treatment as "a non-conventional treatment option."

The court notes that although Plaintiffs read the studies as demonstrating benefit, the question requires a trained medical assessment. While there may be room for debate as to the therapy's value, several of the medical reviewers question the value of and success rate of the therapy and the studies. Plaintiffs assert that the therapy has value for individuals with RSD, but the medical reviewers point to many risks and side effects. The medical reviewers provide an adequate discussion of the issue and the court is not in a position to substitute its own medical judgment. Even if this court were to apply a de novo review, the court could not find that the medical reviewers' opinions in this case were wrong. Rather, the court would need to find some other basis for having them reconsider the issue, such as the appearance of an inadequate review of the studies. But, the medical reviewers in this case provided sufficient analysis and explanations based on their review of the materials. The medical reviewers do not need to parrot the language of the policy in expressing their medical judgments. The medical reviewers can express their judgments, and Altius can apply those judgments to the terms of the Policy in making its decision with respect to benefits. The court, therefore, concludes that Altius' decision should be upheld.

The parties also disputed whether Altius could rely on a provision of a GSA Appendix, referred to as the FDA Exclusion. The FDA Exclusion in the Limitations and Exclusion portion of the GSA Appendix specifically excludes coverage for "medications for non-FDA approved indications." Plaintiffs argue that Altius did not base its decisions on that exclusion throughout the appeals process and that, even if the exclusion is considered, it is a general exclusion that must yield to the specific definition of investigational and experimental found in the GSA. Plaintiff correctly states that Altius cannot find a new basis for denial on appeal. Altius' denial

letters, however, repeatedly informed Plaintiffs of the FDA Exclusion.

The Limitations and Exclusions section is an appendix to the GSA and under the GSA's integration clause, the appendixes are part of the GSA. The fact that the FDA Exclusion includes terms that are defined in another section of the policy does not mean that the exclusion cannot be applied because it is more general than the terms of the definition. The court concludes that there is no basis for finding that Altius could not rely on the FDA Exclusion in denying benefits. In any event, as discussed above, the court concludes that even if the only basis for denial of benefits was the definition of investigational and experimental, there are no grounds for reversing Altius' decision.

Cross Motions to Strike

The parties motions to strike are interrelated and the court will address them together. Plaintiffs move to strike two exhibits to Altius' Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment: (1) Exhibit A which is the FDA required packaging insert for Ketamine, which sets forth the indications for the use of Ketamine; and (2) Exhibit B which is a peer-reviewed study by Michael E. Goldberg, M.D., entitled "Multi-Day Low Dose Ketamine Infusion for the Treatment of Complex Regional Pain Syndrome," published in the journal Pain Physician in 2005 ("Goldberg Study"). Plaintiffs object to the addition of these materials to the record because they relate to the merits of the appeal.

Altius claims that the exhibits relate to Plaintiffs' arguments for a less deferential standard of review based on Altius' alleged conflict of interest. In addition, Altius argues that Plaintiffs put these materials at issue by making inaccurate or misleading allegations based on these materials and it should be able to counter those arguments. Nonetheless, Altius states that it

would not oppose the court striking these exhibits provided that the court grants its Motion to Strike Plaintiffs' references to and reliance upon materials outside the administrative record. In Altius' motion to strike, it aks the court to strike (1) the portions of Plaintiffs' briefing that substantively rely upon evidence not in the record and (2) Plaintiffs' unsupported factual assertion that Ketamine is FDA-approved for use in treating chronic pain in humans.

The first dispute, therefore, relates to whether the court should strike Altius' Exhibit A, which is the FDA insert for Ketamine, and Plaintiffs' assertion that Ketamine is FDA-approved for treating chronic pain. In the briefing of their appeal, Plaintiffs asserted that Ketamine has been approved by the FDA for relief of chronic pain. RSD is a chronic pain condition. However, the FDA has not approved Ketamine for relief of chronic pain. Therefore, Altius attached the FDA insert to counter Plaintiffs' assertions. In their reply on the motion to strike, Plaintiffs withdrew their statement that Ketamine has been FDA-approved for the relief of chronic pain.

The court notes that this issue relates to the merits of the appeal, not the conflict of interest issue. The parties agree that under controlling Tenth Circuit law, materials can be added to the record if they relate to Defendant's potential conflict of interest issue. However, with Plaintiffs' withdrawal of the statement, the need for the FDA insert is moot as is the need to strike the statement. Accordingly, the court strikes Altius' Exhibit A and Plaintiffs' assertion that Ketamine is approved to treat chronic pain.

Next, the court must address whether Altius can attach copies of studies relied on by the medical reviewers. Plaintiffs asserted in their appeal briefing that Altius and the independent reviewers ignored studies and academic literature showing positive outcomes from Ketamine

Infusion Therapy. These studies were repeatedly referenced by Plaintiffs in their appeal letters. Plaintiffs also claim that three of the studies discussed in Altius' technology assessment, one of which was the Goldberg Study, indicated remarkable levels of success. Altius contends, however, that Plaintiffs vastly overstate the conclusions reached in the studies and omit the fact that all three studies expressly concluded that further study was necessary to establish the safety and efficacy of Ketamine Infusion Therapy. Altius states that it included the Goldberg Study as an exhibit because it wanted to demonstrate Plaintiffs' untrue statements regarding the studies that are not present in the administrative record.

Altius also argues that the Goldberg Study is admissible because Altius and the reviewers relied on it during the prelitigation appeals process. Plaintiffs, however, argue that Altius should not be able to cherry pick which study it wants to include for purposes of summary judgment. If the parties copied and submitted articles during the prelitigation appeals, then the articles should be in the record. And, if they did not, then the articles are not part of the record and should not be added on appeal. Although there is some argument that the studies were not properly reviewed in connection with Plaintiffs' arguments as to conflict of interest, the studies mainly relate to the merits of the appeal. The court agrees that Altius should not provide only one of the studies and if the studies are not already apart of the record, they should not be added. Accordingly, the court grants Plaintiffs' motion to strike Altius' Exhibit B, the Goldberg Study.

Furthermore, the court will address whether to strike several of Plaintiffs' references to materials outside the appellate record. Plaintiffs agree that its reference to the 2009 policy language can be disregarded because it is not part of the prelitigation appeal record. Therefore, references to the 2009 policy are stricken. Plaintiffs also reference information on the MCMC

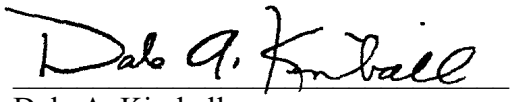
website that is not part of the appellate record. This information relates to MCMC's relationship with its clients and Altius' alleged conflict of interest. The court, therefore, does not believe it is appropriate to strike those references. Accordingly, the parties' motions to strike are granted in part and denied in part, as discussed above.

CONCLUSION

Based on the above reasoning, Defendant's Motion for Summary Judgment is GRANTED and Plaintiffs' Motion for Summary Judgment is DENIED. Plaintiffs' Motion to Strike and Defendant's Motion to Strike are GRANTED IN PART AND DENIED IN PART, as discussed above. The Clerk of Court is directed to close the case. Each party shall bear its and their own fees and costs.

DATED this 15th day of August, 2011.

BY THE COURT:



Dale A. Kimball,
United States District Judge